

Preventing Perinatal Hepatitis B Virus Infection

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Hepatitis B Surface Antigen Prevalence 2006



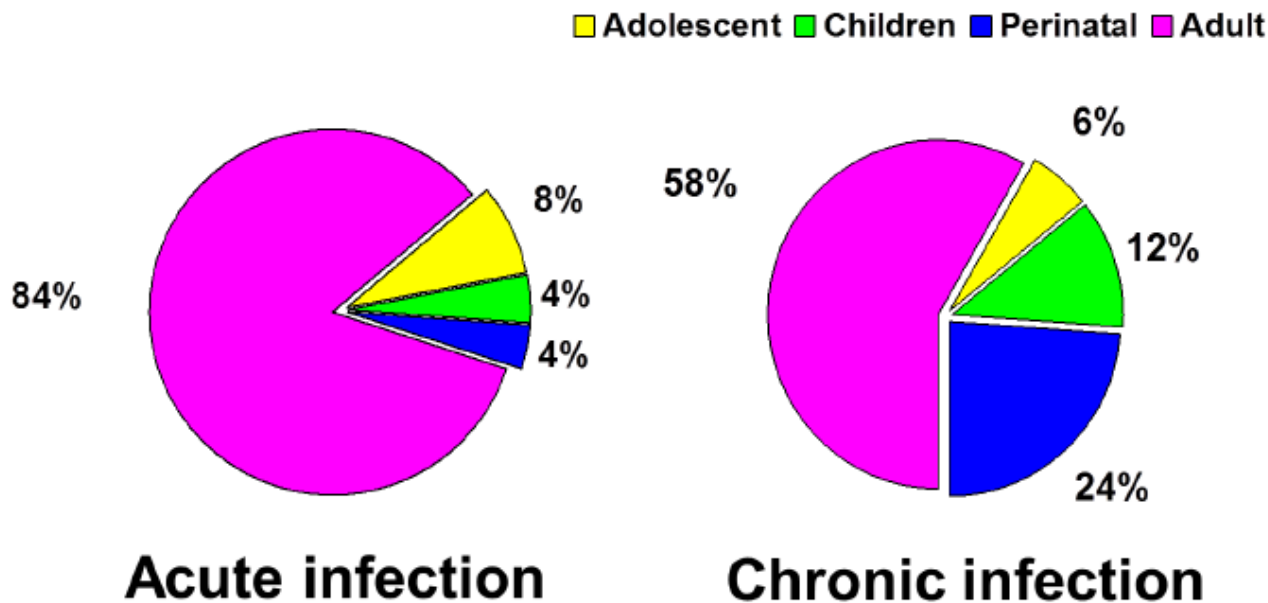
Hepatitis B Virus

- Attacks the liver
- Causes acute and chronic liver disease.
- Spread through contact with the blood or other body fluids of an infected person.
- World-wide:
 - 2,000,000,000 have been infected
 - 240,000,000 chronically infected
 - ~600,000 people die every year
- Hepatitis B virus is 50 - 100 times more infectious than HIV.

US Epidemiology of Hepatitis B Virus

- 700,000-1.4 million people with chronic Hep B
- Estimated 22,000 acute Hep B cases yearly
- Estimated 5,000-8,000 chronically infected yearly
 - Perinatal transmission are 24% of chronic infections
- Without intervention, 90% of infants born to HBsAg+ mothers will be chronically infected

Age of Infection of Acute and Chronic Hepatitis B Virus Infection

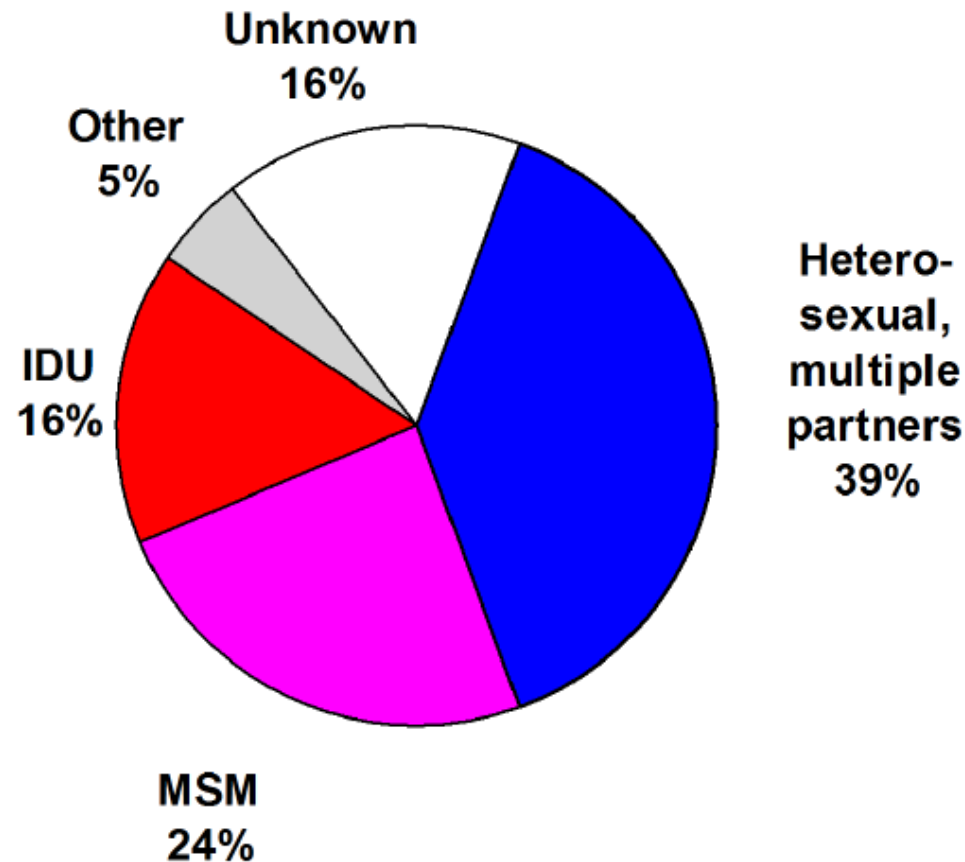


CDC Sentinel Sites. 1989 data.

Risk Factors for HBV Infection

- Multiple sex partners
- Diagnosed with a STD
- Men who have sex with men
- Injection drug users
- Sexual contacts to an HBV infected person
- Hemodialysis patients
- Health care workers
- Born in/parent born in a country with high levels of **chronic HBV infection**.
 - Asia or Pacific Islands
 - Indigenous populations of Alaska, Australia, and New Zealand
 - Areas of South America
 - Areas of the Middle East
 - Africa
 - Caribbean

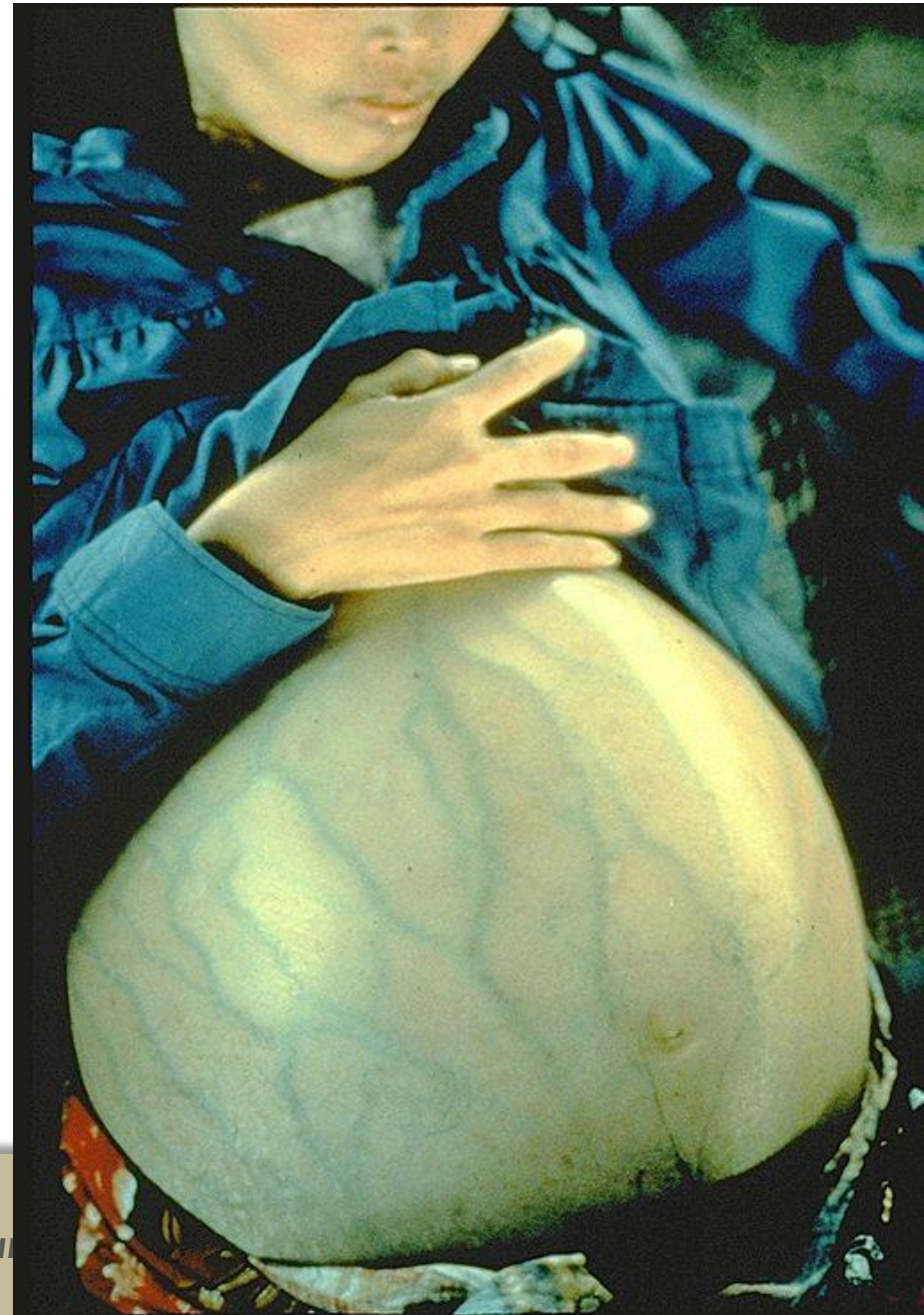
Risk Factors for Hepatitis B Virus Infection



Chronic Hepatitis B

- Liver Cancer
- Cirrhosis

US & Hepatitis B	1979	2007
Cases Diagnosed	15,452	4,519
Deaths	260	719



Hepatitis B Vaccine

- Licensed 1981
- Targeting of high risk 1981-1991
- Comprehensive strategy in 1991
 - Find HBsAg + women and vaccinate infants ASAP
 - Hepatitis B vaccine
 - All infants
 - All adolescents
 - High risk adults

Hepatitis B Vaccine

- Inactive
- Recombinant DNA technology (yeast)
- Efficacy: 90-95%
- 3 doses, IM
- Formulations:
Pediatric, adult,
hemodialysis

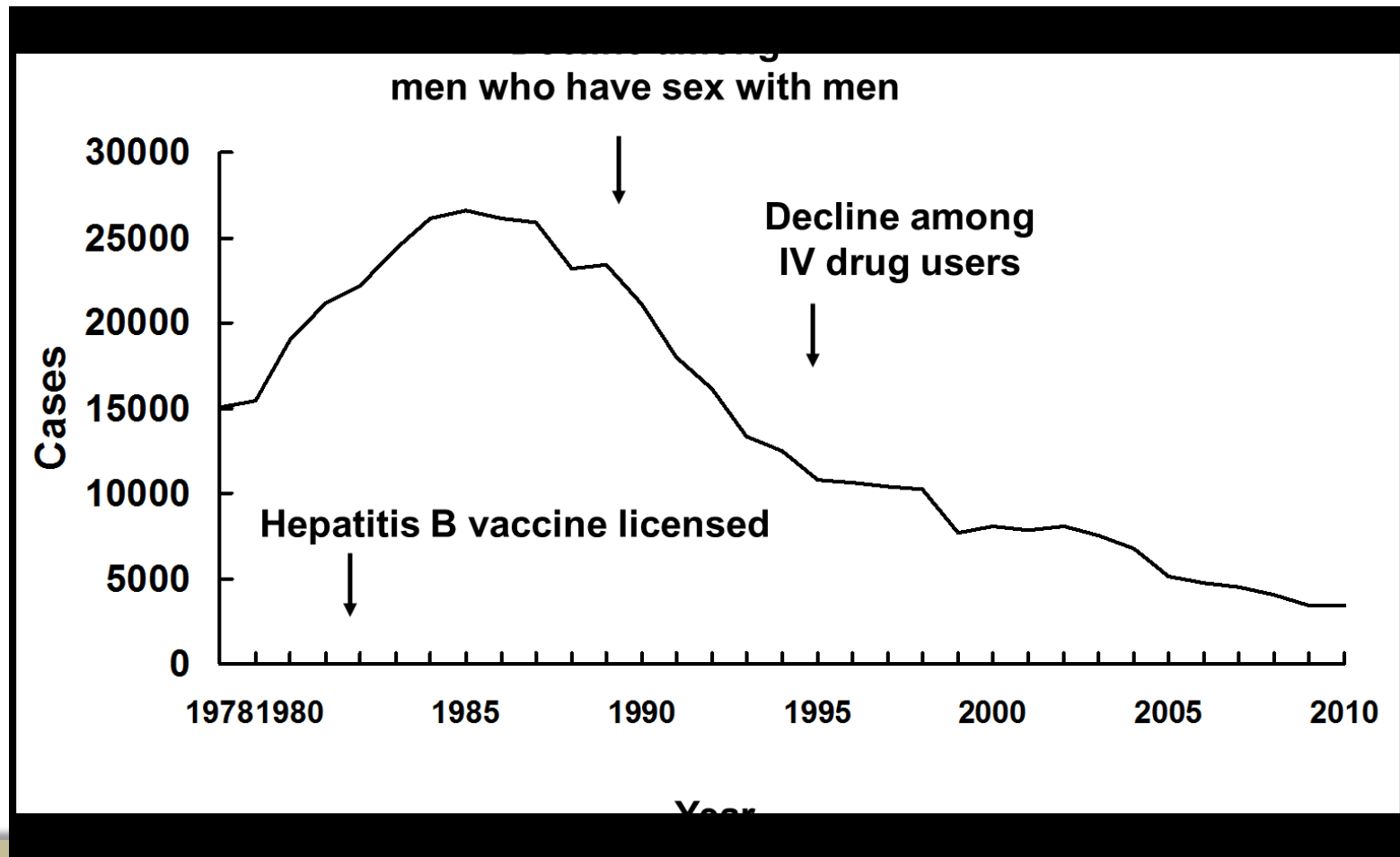
Monovalent:

- Recombivax (Merck)
- Engerix-B (GSK)

Combined:

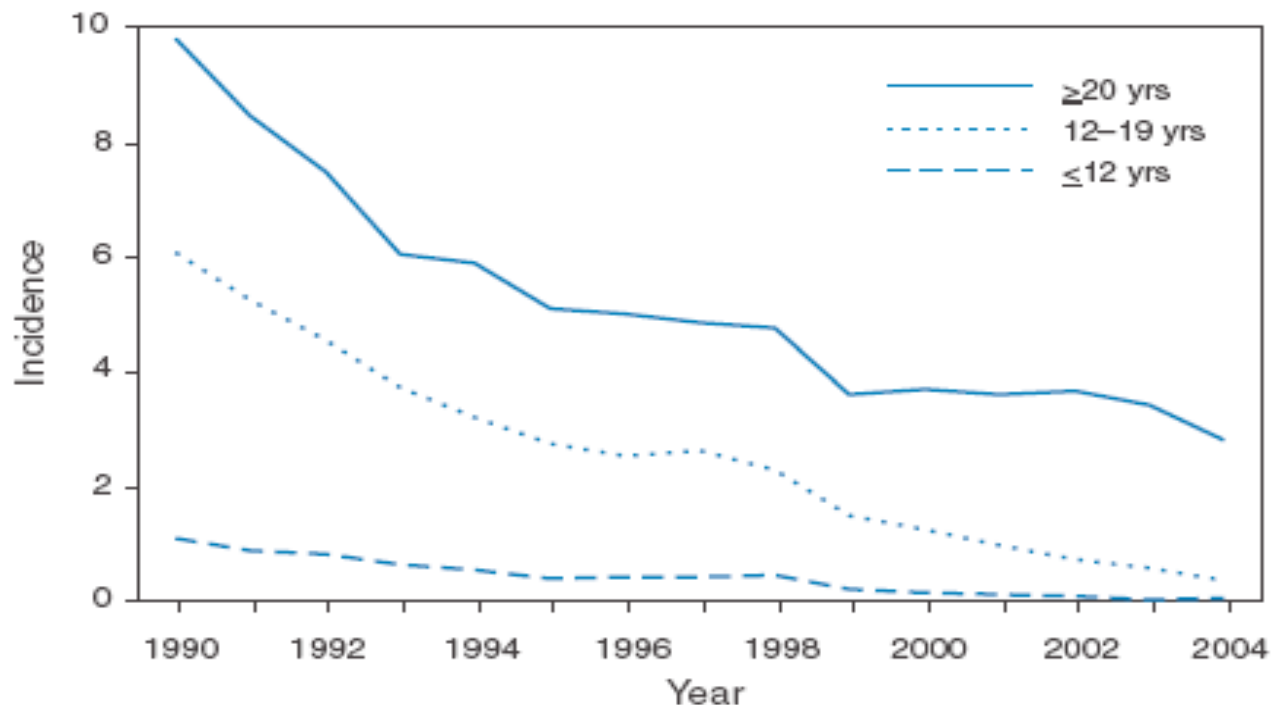
- Pediarix (DTaP-IPV-HBV)
- Comvax (Hib-HBV)
- Adults—Twinrix
(hepatitis A & B)

Hepatitis B—US, 1978-2010



Age of Decrease in Hepatitis B with Vaccination

FIGURE 2. Reported acute hepatitis B incidence,* by age group and year — United States, 1990–2004



* Per 100,000 population.

Perinatal Hepatitis B Virus (HBV) Prevention Program

1. Screen all pregnant women for HBV infection (HBsAg+)
2. Give hepatitis B vaccine and hepatitis B immune globulin (HBIG) within **12** hours of birth to infants of HBsAg+ mothers
3. Give remaining hepatitis B vaccines to infant as soon as possible as recommended
4. Check infant's serology after immunization to see if immune or infected

Gaps in Hospital Policies for Perinatal Hepatitis B Prevention

- Survey/record review
 - 190 hospitals in 50 states, PR, DC
 - 4762 mothers
 - 4786 infants
 - 18 HBsAg + moms
 - 320 infants with UNKNOWN mom status
- HBsAg+ moms
- 62% vaccine & HBIG in 12 hrs
 - 14% no vaccine before D/C
 - 20% no HBIG before D/C
- HBsAg UNKNOWN moms
- 52% vaccine within 12 hrs
 - 20% no vaccine before D/C
- HBsAg NEGATIVE moms
- 69% vaccine before D/C

ADHS Study

- Comparing infants getting hep B vaccine within 3 days versus ≥ 14 days
 - Children of mothers who experienced **complications** during labor or delivery
 - More than 2x as likely to miss the hep B vaccine birth dose
 - Children of mothers with **private** insurance
 - Approximately 2x as likely to miss the hep B vaccine birth dose

Perinatal Hepatitis B Prevention Program Manual



Arizona Department of Health Services

Arizona Immunization Program Office

9/26/2012

Leader

<http://www.azdhs.gov/phs/immun/perihepb.htm>



Perinatal Hepatitis B Prevention

- Screen for all pregnant women for HBsAg
- Monovalent vaccine and HBIG within 12 hours
 - When HBsAg+ mom
 - Premature infants with UNKNOWN mom's status
- Monovalent Hep B vaccine within 12 hours if term with UNKNOWN mom's status
- Hep B vaccine in all kids before hospital D/C
- Finish hep B vaccine series ASAP for infants whose mothers are HBsAg +
- HBsAg and anti-HBs on infants with HBsAg + moms

Obstetrician Responsibilities

- Correct screening test (HBsAg) on all pregnant women in every pregnancy
- Send screening test results to delivery hospital
- Notify County Health Department of positive HBsAg test
- Educate HBsAg + woman about hep B virus and need for infant to get vaccine and HBIG within 12 hours

Hospitals' Responsibilities

- Have written perinatal hepatitis B policy
- Know HBsAg status of all delivering mothers
- Give infant hep B vaccine and HBIG within 12 hours of birth if
 - Mother HBsAg POSITIVE
 - Infant < 2 kg and mother's HBsAg status UNKNOWN
- Give infant hep B vaccine within 12 hours if ≥ 2 kg and mother's HBsAg status UNKNOWN
- Give hep B vaccine to all infants before D/C
- Educate HBsAg POSITIVE mother that the infant will need additional hep B vaccines and blood tests

Pediatricians' Responsibilities

- Order hep B vaccine and HBIG within 12 hours for infants if
 - Mother HBsAg POSITIVE
 - Infant < 2 kg and mother is HBsAg UNKNOWN
 - **Do not count this first hep B vaccine dose if < 2 kg**
- Give hep B vaccine within 12 hours if infant >2kg and mother is HBsAg UNKNOWN
- HBsAg exposed infants need full hep B series ASAP
- Test infant 3 months after last hep B vaccine for HBsAg and antibody to HBsAg (anti-HBs)
- Report vaccines doses and serology results to CHD

Checklists in ADHS Perinatal Hepatitis B Prevention Program Manual

ADMISSION ORDERS and PROCEDURES FOR BIRTHING MOTHERS to Prevent Perinatal Hepatitis B Virus Infection (cont.)	
Checklist #2 for Pregnant women who do <u>not</u> have a copy of their <i>actual</i> prenatal HBsAg laboratory report from this pregnancy available on admission	<input checked="" type="checkbox"/>
1. Order an HBsAg blood test on the woman, even if she had been previously tested. <ul style="list-style-type: none"> Order the woman's HBsAg test to be done as soon as possible, unless delivery is not imminent. Make sure that the woman's HBsAg test is done in a timely manner so that the woman's HBsAg result is placed on her chart and placed on her infant's chart and communicated to the woman's physician, to the nursery staff, and to the infant's physician before delivery. 	
2. Instruct the laboratory to call Labor & Delivery and the nursery staff with the delivering pregnant woman's newly obtained HBsAg test result as soon as possible .	
3. Once the pregnant woman's HBsAg laboratory report is available: <ul style="list-style-type: none"> Make sure that the correct test was performed. [The correct test is HBsAg (hepatitis B surface antigen). Do not confuse this with other hepatitis B virus (HBV) tests.] Place a copy of the HBsAg laboratory report into (1) the mother's Labor & Delivery record and (2) the infant's hospital record. If the HBsAg test is POSITIVE, make sure that the nursery staff and the infant's physician are aware of the test result and that the infant must receive both hepatitis B vaccine (HepBVacc) and hepatitis B immune globulin (HBIG) within 12 hours of birth. 	

Vaccine Guidance in ADHS Perinatal Hepatitis B Prevention Program Manual

Table 4-1
Term* Infant HepBVacc and HBIG Schedule
Based on Mother's HBsAg Status

Term Infants born to HBsAg-POSITIVE Women		
Biologic	Age of Infant	IM Dose
HBIG	Within 12 hours of birth [§]	0.5 mL
HepBVacc 1 [#]	Within 12 hours of birth [§]	0.5 mL
HepBVacc 2	1-2 months (6 weeks-2 months if using combination vaccines) ^Δ	0.5 mL
HepBVacc 3	6 months [¶]	0.5 mL
Term Infants Born to Women Whose HBsAg Status is UNKNOWN		
Biologic	Age of Infant	IM Dose
HepBVacc 1 [#]	Within 12 hours of birth	0.5 mL
HepBVacc 2	1-2 months (6 weeks-2 months if using combination vaccines) ^Δ	0.5 mL
HepBVacc 3	6 months [¶]	0.5 mL
HBIG	Defer giving HBIG pending result of mother's test for HBsAg. If mother found to be HBsAg-POSITIVE, give infant HBIG as soon as possible but within 7 days of birth.	0.5 mL
Term Infants Born to HBsAg-NEGATIVE Women		
Biologic	Age of Infant	IM Dose
HepBVacc 1 [#]	Birth (before discharge)	0.5 mL
HepBVacc 2	1-2 months (6 weeks-2 months if using combination vaccines) ^Δ	0.5 mL
HepBVacc 3	6-18 months [¶]	0.5 mL

Term Infants born to HBsAg-POSITIVE Women

Biologic	Interventions
HBIG	Within 12 hours of birth
Vaccine* Dose 1	Within 12 hours of birth
Vaccine* Dose 2	1-2 months (6 weeks-2 months if using combination vaccines)
Vaccine* Dose 3	6 months

* Monovalent hepatitis B vaccine

Term: Weight \geq 2 kg

Term Infants born to HBsAg-NEGATIVE Women

Biologic	Interventions
HBIG	None
Vaccine* Dose 1	Before discharge
Vaccine* Dose 2	1-2 months
Vaccine* Dose 3	6-18 months

* Monovalent hepatitis B vaccine

Term: Weight \geq 2 kg

Term Infants born to HBsAg-UNKNOWN Women

Biologic	Interventions	
Vaccine* Dose 1	Within 12 hours of birth	
HBIG	Test mother for HBsAg. Defer giving HBIG pending mother's result.	
	HBsAg POSITIVE Mother	HBsAg NEGATIVE Mother
	Give infant HBIG ASAP but within 7 days of birth.	No HBIG needed
Vaccine* Dose 2	1-2 months	
Vaccine* Dose 3	6 months	6-18 months

Term: Weight ≥ 2 kg



Leadership for a Healthy Arizona

* Monovalent hepatitis B vaccine

Preterm Infants born to HBsAg-POSITIVE Women

Biologic	Interventions
Vaccine* Birth Dose	Within 12 hours of birth
HBIG	Within 12 hours of birth
Vaccine* Dose 1	1 month
Vaccine* Dose 2	2 months
Vaccine* Dose 3	6 months

* Monovalent hepatitis B vaccine

Preterm: Weight < 2 kg

Preterm Infants born to HBsAg-NEGATIVE Women

Biologic	Interventions
Vaccine* Dose 1	1 month or by time of hospital discharge
Vaccine* Dose 2	2 months
Vaccine* Dose 3	6-18 months

* Monovalent hepatitis B vaccine

Preterm: Weight < 2 kg

Preterm Infants Born to HBsAg-UNKNOWN Women

Biologic	Interventions	
Vaccine* Birth Dose	Within 12 hours of birth	
HBIG	Within 12 hours of birth (unless mother can be shown HBsAg-NEGATIVE within 12 hours of birth)	
	HBsAg POSITIVE mom	HBsAg NEGATIVE mom
Vaccine* Dose 1	1 month	1 month
Vaccine* Dose 2	2 months	2 months
Vaccine* Dose 3	6 months	6-18 months

* Monovalent hepatitis B vaccine

Preterm: Weight < 2 kg

Routine Infant Monovalent Hepatitis B Vaccine Schedule

Dose	Usual Age	Minimum Interval
1	Birth	---
2	1-2 months	4 weeks
3	6-18 months*	8 weeks#
*Give the 3 rd dose at 6 months to infants whose mothers are HBsAg-POSITIVE or HBsAg status UNKNOWN.		#At least 16 weeks after the first dose. 3rd dose should <u>not</u> be before 24 weeks old.

Vaccine Schedule for Term Infant if Pediarix® (DTaP-HBV-IPV) Is Used

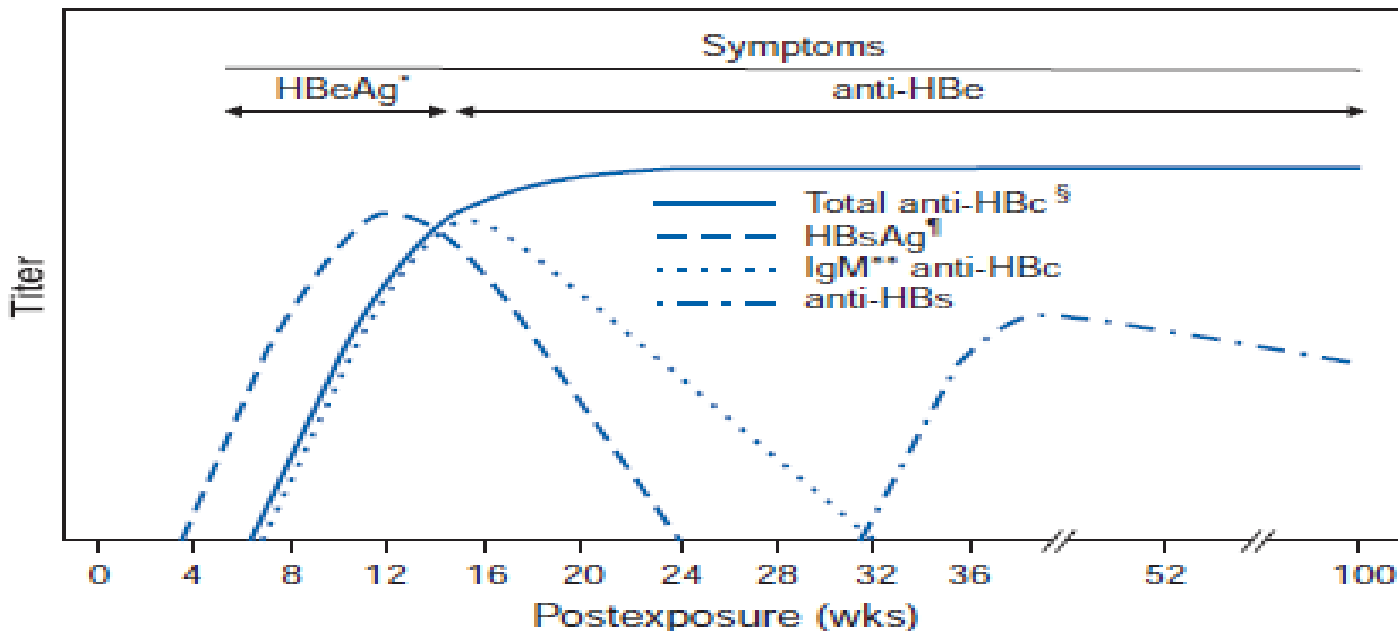
Biologic	Age of Infant
Monovalent vaccine—Dose 1	Birth
Pediarix®-- Dose 2	2 months
Pediarix®-- Dose 3	4 months
Pediarix®-- Dose 4	6 months
Pediarix® cannot be used at birth, before 6 weeks, or at ≥ 7 years.	

Vaccine Schedule for Term Infant if Comvax® (HBV-Hib) Is Used

Biologic	Age of Infant
Monovalent vaccine—Dose 1	Birth
Comvax®-- Dose 2	2 months
Comvax®-- Dose 3	4 months
Comvax®-- Dose 4	12-15 months
Comvax® cannot be used at birth, before 6 weeks, or at ≥ 6 years old.	

Laboratory results in Acute Hepatitis B Infection

FIGURE 1. Typical serologic course of acute hepatitis B virus infection with recovery



* Hepatitis B e antigen.

† Antibody to HBeAg.

§ Antibody to hepatitis B core antigen.

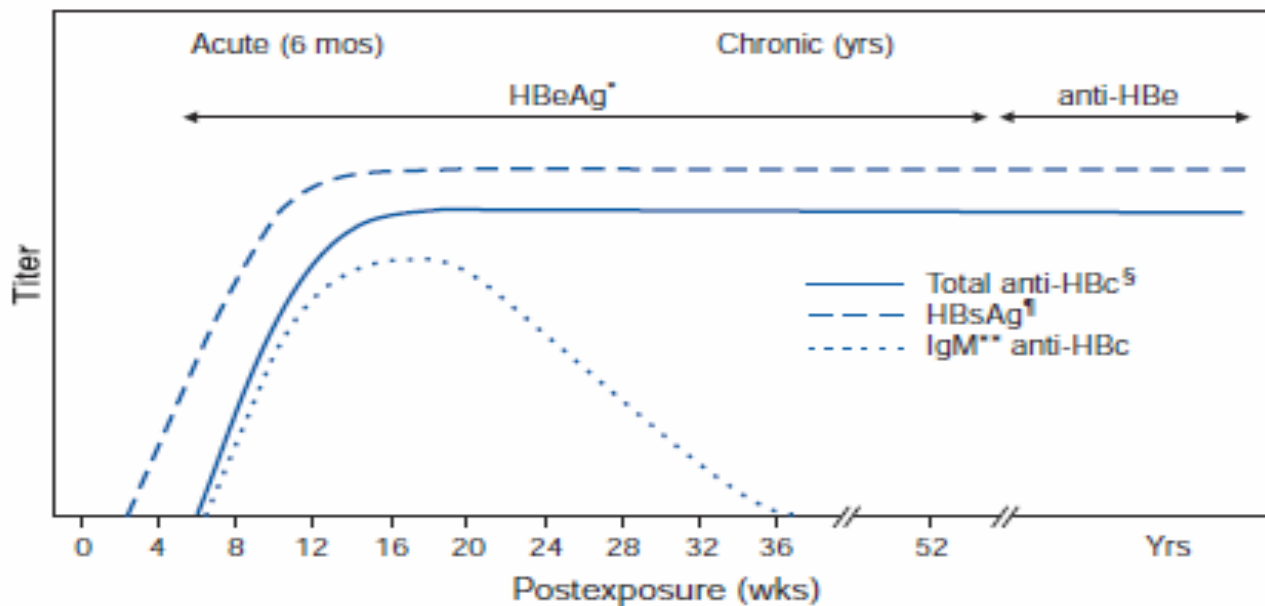
† Hepatitis B surface antigen.

** Immunoglobulin M.

†† Antibody to HBsAg.

Laboratory results in Chronic Hepatitis B Infection

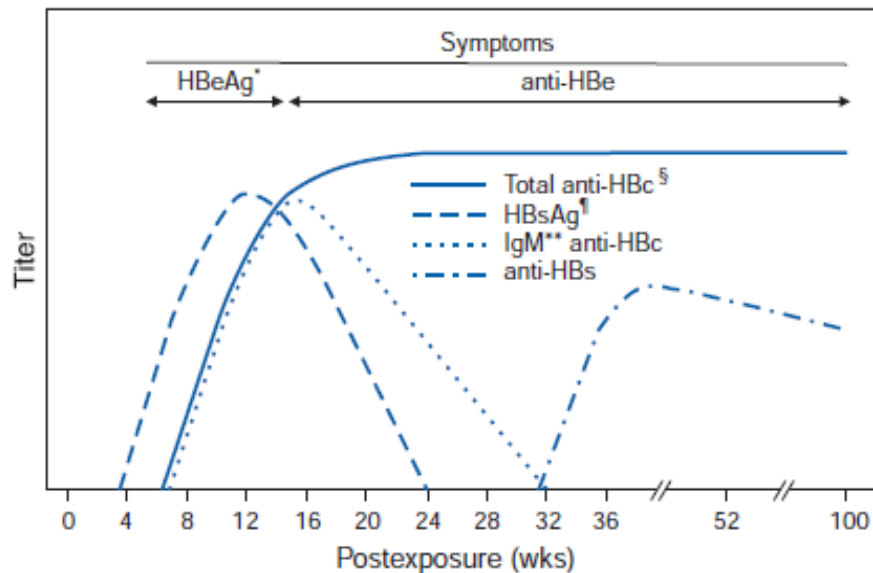
FIGURE 2. Typical serologic course of acute hepatitis B virus (HBV) infection with progression to chronic HBV infection



- * Hepatitis B e antigen.
- † Antibody to HBeAg.
- § Antibody to hepatitis B core antigen.
- † Hepatitis B surface antigen.
- ** Immunoglobulin M.

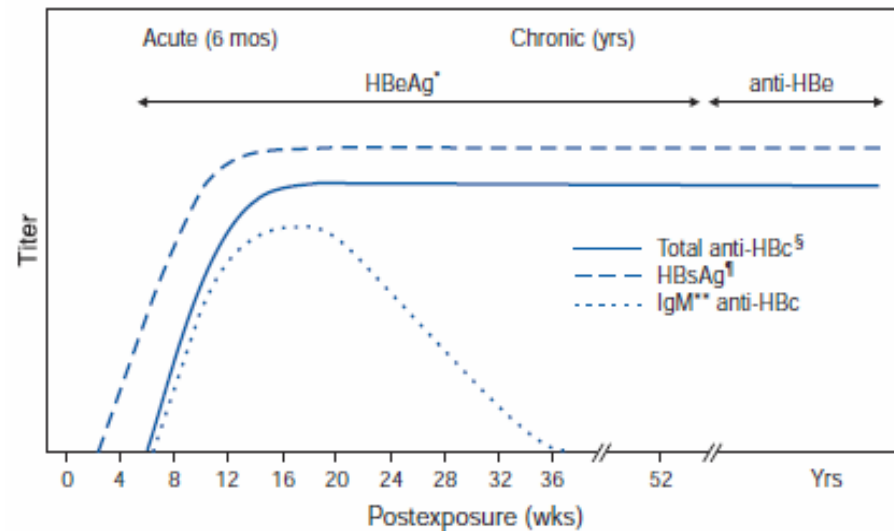
Laboratory results in Acute vs Chronic Hepatitis B Infection

FIGURE 1. Typical serologic course of acute hepatitis B virus infection with recovery



- * Hepatitis B e antigen.
- † Antibody to HBeAg.
- § Antibody to hepatitis B core antigen.
- † Hepatitis B surface antigen.
- ** Immunoglobulin M.
- †† Antibody to HBsAg.

FIGURE 2. Typical serologic course of acute hepatitis B virus (HBV) infection with progression to chronic HBV infection



- * Hepatitis B e antigen.
- † Antibody to HBeAg.
- § Antibody to hepatitis B core antigen.
- † Hepatitis B surface antigen.
- ** Immunoglobulin M.

Interpretation of Maternal Hepatitis B Virus (HBV) Serology Results

Tests	Results	Interpretation	Recommendations
HBsAg	Positive	Mother infectious for HBV	<ul style="list-style-type: none">• Baby will need vaccine and HBIG within 12 hours of birth• Notify delivery hospital• Notify county health department• Educate mother• Refer mother for GI care

Interpretation of Maternal Hepatitis B Virus (HBV) Serology Results

Tests	Results	Interpretation	Recommendations
HBsAg	Negative	Not infectious for HBV	<ul style="list-style-type: none">Baby will need 1st hepatitis B vaccine before discharge

Interpretation of Infant Hepatitis B Virus (HBV) Serology Results after Last Dose

Tests	Results	Interpretation	Recommendations
HBsAg	Positive	Infant infected with HBV	<ul style="list-style-type: none">• GI referral for care• Educate parents
anti-HBs	Negative		

Interpretation of Infant Hepatitis B Virus (HBV) Serology Results after Last Dose

Tests	Results	Interpretation	Recommendation
HBsAg	Negative	Not infectious	Celebrate
anti-HBs	Positive	Protective immunity	

Interpretation of the Infant Hepatitis B Virus (HBV) Serology Results

Tests	Results	Interpretation	Recommendation
HBsAg	Negative	Not infected	Repeat 3 doses of HBV vaccine and recheck serology
anti-HBs	Negative	Not protected	

ADHS Perinatal Hepatitis B Virus Prevention Manual

- ADHS website
 - Arizona Immunization Program→
 - Information for Health Care Professionals→
 - Perinatal Hepatitis B Program

<http://www.azdhs.gov/phs/immun/perihepb.htm>
- Telephone: (602) 364-3630
- Email: geneva.alvarado@azdhs.gov

Summary of Perinatal Hepatitis B Virus Prevention Program

1. Screen all pregnant women for HBsAg
2. Give hepatitis B vaccine and hepatitis B immune globulin (HBIG) within **12** hours of birth to infants of HBsAg POSITIVE mothers
3. Give all infants hep B vaccine before discharge
4. Give remaining hep B vaccines to HBsAg exposed infant ASAP
5. Check HBsAg exposed infant's serology for **HBsAg and anti-HBs** after last immunization to see if immune or infected